



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Memorandum

Date August 10, 1999

From Division of Product Manufacture and Use; Chemistry Review Team, HFS-246

Subject FAP 9A4652: Procter and Gamble Co. Olestra in Ready-to-Heat Popcorn. Milestone 2.0. Submission of 2-25-99.

To M. Ditto Ph.D.  
Division of Product Policy, HFS-206

Procter and Gamble (P&G) is petitioning to amend 21 CFR 172.867 (Olestra) to permit the use of olestra as a substitute for oil in pre-packaged, ready-to-heat popcorn. Examples of such products would be microwave popcorn, or "Jiffy Pop". The use of olestra for the preparation of ready-to-eat popcorn is already permitted under §172.867. P&G also seeks to reference the specifications monograph published in the 1st Supplement (1997) to the 4th Edition of the Food Chemicals Codex.

Olestra's identity is delineated in the regulation and requires no further discussion here. The manufacture of olestra, as well as analytical methodology for its quantification in food, have been documented in FAP 7A3997 and will also not be reconsidered here. The probable exposure of olestra from this use has been taken into consideration during the review of FAP 7A3997 prior to the promulgation of §172.867, as the method of preparation of the popcorn would not be expected to affect its, and therefore olestra's, intake.

At issue in this submission is the potential for degradation on cooking of vitamins A, D, E, and K, which are added to the unpopped corn to meet the requirements of §172.867. P&G has submitted data describing the conditions encountered by vitamins A, D, E, and K during the cooking of ready-to-heat popcorn. They state that under typical conditions, the temperature in a microwave bag of popcorn reaches a maximum temperature of 175°C. Further, they note that this temperature is attained for only approximately 30 seconds (Exhibit 3). They state that endogenous fat-soluble vitamins are often submitted to harsher conditions during the commercial preparation of foods.

P&G has submitted a rationale for using their data from microwave-processed popcorn for all ready-to-heat popcorns. They note that microwaving is the method of choice among consumers of popcorn prepared at home (~80% of home made popcorn). Also, they state that the heating of lipid as a heat-transfer agent is used to cook the popcorn in both microwave and stove top applications, ensuring that the unpopped corn is experiencing similar cooking conditions. We agree that using data derived from microwaved popcorn is adequate.

P&G (through Covance, a contract laboratory) has analyzed samples from 10 lots of popcorn (containing, on average, 30.7% olestra) after microwaving, determining that 44% of vitamin A, 4.3% of vitamin D, and 24.4% of vitamin K are lost during cooking (Exhibit 5, detailed discussion at Section 3.3, pp. 023-027). They state that vitamin E loss during cooking was considered in FAP 7A3997 and found to be 3-4%, under harsher conditions than those encountered during the heating of microwave popcorn. The nutritional implications of these losses are considered in section 3.4. We do

not have any comments concerning this discussion and suggest that agency experts in nutrition be consulted concerning this information and its ramifications. We have no questions concerning the fat-soluble vitamin decomposition data.

P&G has included a discussion of the safety of the degradation products of the fat-soluble vitamins. They state that consumers are regularly exposed to these materials from the consumption of cooked foods. There is no numerical discussion of exposure to these degradation products. Regardless, we concur that the exposure to fat-soluble vitamin degradation products from this use of olestra would be similar to, or less than, that from other foods fried in oils, or otherwise cooked. Further, P&G reports that data concerning the consumption of microwave popcorn show that it is eaten infrequently (2 times in 14 days, on average) and rarely with meals (the consumption of olestra with foods containing fat-soluble vitamins is believed to result in the largest impact on fat-soluble vitamin absorption). We concur.

The 4th Edition, 1st supplement of the Food Chemicals Codex contains a specifications monograph for olestra, which P&G seeks to have referenced in §172.867. The monograph contains specifications for assay, free fatty acids, heavy metals, lead, residual methanol, residue on ignition, peroxide value, water, and stiffness (thixotropy) that are identical to the specifications in the regulation. The identity section of the monograph agrees with §172.867 as it pertains to permitted levels of fatty acids, the level of unsaturation, and the degree of esterification of olestra. We concur that the monograph should be referenced in the regulation.

The proposed regulation is acceptable.

We have no questions concerning this submission at this time.



Michael DiNovi, Ph.D.

